REMARKS

Claims 1 to 16 are presently pending. Claim 8 has been amended to remove the multiple dependency. Claim 9 has been amended to more clearly define the isolated population of progenitor cells having a CD45-/CD123+ phenotype. Claim 10 has been added to further define the CD45-/CD123+ cells as cells obtained by non-static non-adherent suspension culturing in serum-deprived nutrient medium. Support for the amendment can be found in the specification on page 9, 1st and 2nd paragraphs and in the Examples at pages 16-19. Claims 1, 2, 6, 7, 8, 9, and 10 have been amended to recite that the cell population can comprise both stem and progenitor cells. Support for this amendment is found as follows: page 4, line 4; page 5, line 22; and page 8, line 3. New claims 11 and 12 have been added. These claims are directed to the actual cell culture composition of stem and/or progenitor cells in non-static, non-adherent suspension culture in serum-deprived nutrient medium. Support is found throughout the application (for example, the first paragraph under "Summary of the Invention"). New claim 13 is added. It is directed to the additional step of isolating the cells and forming a pharmaceutical composition. New claim 14 is directed to the actual pharmaceutical composition produced by this process. Support is found in the application *inter alia* in the paragraph spanning pages 9 and 10. New claims 15 and 16 have been added. They are directed to the cell source. Support can be found page 8, lines 17-19.

No new matter is added by the present amendments.

Claim Objections

The Examiner objected to claim 8 under 37 CFR 1.75(c) as being in improper form on the basis that a multiple dependent claim cannot serves as the basis for another multiple dependent claim. The Examiner stated that claim 8 has not been further treated on the merits.

Claim 8 has been amended to remove the multiple dependency. As presently amended, claim 8 depends solely from independent claim 1. Reconsideration and withdrawal of the Examiner's rejection is respectfully requested.

Claim Rejections – 35 USC § 102

The Examiner rejected claims 1-7 and 9 under 35 USC 102(b) as being anticipated by Baksh et al (WO02/086104).

The Examiner stated at page 2, last paragraph bridging page 3, first paragraph of the Office Action:

> "Baksh et al. teach the following: "[0048] FIG. 1D shows various types of differentiated cells induced from the parenchymal progenitor cell population, grown in the presence of defined cytokine cocktails. The cytokine concentrations used were 10 ng/ml (stems cell factor) (SCF), 2 ng/ml interleukin-3 (IL3), 100 ng/mJ macrophage colony stimulating factor (MCSF), and 30 ng/ml platelet-derived growth factor (PDGF)." This aspect of the Baksh et al. invention teaches culturing of non-hematopoietic cells in the presence of a serum-free medium. (Underlining added)

Present claim 1 is a process claim reciting the use of both (1) serum-deprived medium, and (2) non-static, non-adherent suspension culturing, as a means for culturing a progenitor cell population. Baksh et al does not describe a culturing process that incorporates both of these features. Rather, for the culturing of progenitor cells, Baksh et al use either (a) non-static, non-adherent suspension culturing of progenitor cells in a serum-containing medium, or (b) culturing of progenitor cells in serum-deprived medium but on plates, i.e., in an adherent, static environment. Essentially, Baksh et al describe the use of non-static suspension culturing in serum to expand progenitor cell numbers, and then differentiating the expanded progenitors by plating in defined media. In neither case do Baksh et al teach the combined use of serum-deprived medium to culture progenitors by non-static, non-adherent suspension.

More particularly, the culturing of progenitor cells by stirred suspension is performed by Baksh et al using MyeloCult medium (Example 1). This is a long term culturing (LTC) medium sold by Stem Cell Technologies that contains both horse serum and fetal bovine serum. As noted in Example 1:

> "Stirred suspension bioreactors were initiated with 8.5×10^6 cells suspended in Myelocult™ medium for 20 days. Each bioreactor received a different treatment that

included no cytokines, SCF + IL-3, SCF + PDGF, or PDGF. At days 5, 10, 15 and 20, half the medium was removed and replaced with fresh medium containing the appropriate cytokine supplementation. The cells were counted and plated in a CFU-F and bone nodule assay at a cell seeding density of 1 x 10^4 cells/cm^2. ... Figure 1D shows the morphology of cells differentiated from the expanded progenitors." (underlining added).

Clearly, Baksh et al culture first in serum when stirred suspension is applied to expand progenitor numbers, and then switch to static, adherent conditions, i.e., plating, when inducing the cells to differentiate.

Thus, when stirred suspension culturing is used, Baksh et al utilize a medium that is not serum-deprived, but is essentially serum-based.

On the other hand, Baksh et al also describe protocols useful to induce differentiation of the progenitor cells expanded in the presence of serum. As noted on page 13 and in the protocols describing the CFU-F and CFU-O assays on page 18, Baksh et al describe culturing in the presence of a defined medium. This culturing is performed on plates or in a flask, however, which provide adherent or at least static environments, and not the non-static, non-adherent suspension conditions required by claim 1.

Thus, the growth medium used to culture the progenitor cells in Baksh et al clearly either contains a substantial amount of serum or, assuming serum is not present, is not used under the non-static, non-adherent suspension conditions required by claim 1. Accordingly, Baksh et al. fails to disclose each and every element of independent claim 1.

Claim 9 is for a cell population characterized by a CD45-/CD123+ phenotype. The Examiner submits that the Baksh et al technology would inherently produce such cells, absent evidence to the contrary.

As noted in the specification, the inventors themselves were surprised to find that serum-free suspension culturing supported the growth of CD45- cells that were also positive for the IL-3α receptor (CD123+). The prior art had hypothesized that any influence of IL-3 in the culturing medium was through interaction with CD45+ (hematopoietic) cells, which then responded to IL-3 by releasing factors that influenced growth of CD45- cells. This hypothesis does not

accommodate a cell that is both mesenchymal (CD45-) and responsive directly to IL-3. Without this knowledge, as now documented by the present inventors in paragraphs [0058] – [0070], there would be no motivation even to look within the culture for a progenitor cell having this phenotype, let alone seek to isolate such a cell, as required by claim 9. Thus, even if the Baksh et al teachings would inherently produce the cell of claim 9, which is not known to be the case, there is no teaching in Baksh et al to isolate such a cell and, accordingly, no anticipation of claim 9 which requires the cells in isolated form.

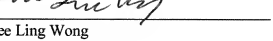
For at least the reasons set out above, it is respectfully submitted that the subject matter of independent claims 1 and 9 is not anticipated by Baksh et al. For the same reasons, it is respectfully submitted that the subject matter of dependent claims 2-7 and 10 which depend directly or indirectly from independent claims 1and 9 is also not anticipated by Baksh et al.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

A Petition for an Extension of Time requesting an extension of two months for filing the subject response is attached. The Commissioner is authorized to charge any deficiency or credit any overpayment in the fees for same to our Deposit Account No. 500663.

Date: November 10, 2009

JOHN E. DAVIES; DOLORES BAKSH;
PETER ZANDSTRA

By: 

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Att. Petition for Extension of Time